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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|----------------------|---------------------|------------------|
| 09/457,931 | 12/08/1999 | H. RALPH SNODGRASS | 441472000100 | 8228 |
| 25226 | 7590 | 03/22/2004 | EXAMINER | |
| MORRISON & FOERSTER LLP | | | CHEN, SHIN LIN | |
| 755 PAGE MILL RD | | | ART UNIT | PAPER NUMBER |
| PALO ALTO, CA 94304-1018 | | | 1632 | |

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/457,931

Applicant(s)

SNODGRASS, H. RALPH

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-20 and 34-56 is/are pending in the application.
- 4a) Of the above claim(s) 19, 20 and 34-41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-18 and 42-46 is/are ~~allowed~~ allowable.
- 6) ☒ Claim(s) 47-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>9-5-00</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-14-03 has been entered.

Applicant's amendment filed 10-14-03 has been entered. Claims 2, 3, 5, 7 and 10-18 have been amended. Claims 21-33 have been canceled. Claims 42-56 have been added. Claims 2-20 and 34-56 are pending and claims 2-18 and 42-56 are under consideration.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

There are **two** "claim 50" in the newly added claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 47-56 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to prioritize drug development just by comparing an expression profile of a test chemical composition with a library of expression profiles of chemical compositions, and what is the correlation between the rank or type of toxicity of the test chemical composition and the priority of drug development. Claims 48-56 depend on claim 47 but fail to clarify the indefiniteness.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 48, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 48, 50 and 51 are directed to a method for prioritizing drug development of a test chemical comprising prioritizing drug development of the test chemical by comparing expression profile of the test chemical composition with a library of expression profiles of chemical compositions, wherein the test chemical composition **is known or unknown**.

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Since the test chemical composition is unknown, it is apparent that the applicant does not have possession of said test chemical composition at the time of the invention. The specification fails to provide any disclosure for the **unknown** test chemical composition, therefore, the specification fails to reasonably convey to one skilled in the art that applicants were in possession of all the unknown test chemical composition. Thus, it is concluded that the written description requirement is not satisfied for the claimed unknown test chemical composition.

7. Claims 47-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 48, 50 and 51 are directed to a method for prioritizing drug development of a test chemical comprising prioritizing drug development of the test chemical by comparing expression profile of the test chemical composition with a library of expression profiles of chemical compositions, wherein the test chemical composition is known or unknown and the mammalian embryoid body can be human or non-human embryoid body.

The specification only indicates that the information of the toxicity of the test chemical composition can be used for prioritizing drug development, however, the specification fails to provide adequate guidance for how to prioritize drug development based on the rank or type of toxicity of the test chemical composition either known or unknown. The specification fails to provide adequate guidance as to what extent of the rank or type of the toxicity of the test chemical composition would qualify the priority of said test chemical composition for drug

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development. The correlation between the rank or type of toxicity of the test chemical composition and the priority of drug development is absent. One skilled in the art at the time of the invention would not know how to prioritize drug development just by comparing an expression profile of a test chemical composition with a library of expression profiles of chemical compositions. Further, as discussed above, applicant does not have possession of the **unknown** test chemical compositions and would not be able to prioritize drug development for the unknown test chemical compositions. Thus, it would have required one skilled in the art at the time of the invention undue experimentation to practice the full scope of the invention claimed.

Information Disclosure Statement

8. The references DE 19606207 and WO 97/01644 cited in the information disclosure statement filed 9-5-00 fail to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Conclusion

Claims 47-56 are rejected. Claims 2-18 and 42-46 are in condition for allowance.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for this group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'Shin-Lin Chen' in a cursive style.